Remarks

I. Support for the Amendments

Of the 11 original claims, non-elected claims 3-11 have been canceled without disclaimer of or prejudice to the underlying subject matter, and claim 1 has been amended. Claims 12-17 have been added. Support for the foregoing claim amendments may be found throughout the specification, for example at page 9, lines 18-23 and at page 19, lines 9-23, in the sequence listing and in the original claims. Upon entry of the foregoing amendments, claims 1, 2, and 12-17 are pending in the application. No new matter enters by these amendments.

The specification has been amended to remove embedded hyperlinks and/or other forms of browser-executable code. No new matter enters by these amendments. The URL addresses themselves contained throughout the specification do not constitute browser-executable code in the absence of embedded hyperlinks and/or other forms of browser-executable code. The specification as amended does not contravene stated PTO policy of prohibiting live web links to other web pages, which might be commercial. (MPEP, § 608.01 (d).)

II. The Restriction Requirement

Applicants acknowledge the finality of the restriction requirement but maintain their traversal. To facilitate prosecution, however, Applicants have removed the non-elected claims from the application.

Applicants also acknowledge the finality of the election requirement to a single nucleotide sequence, but maintain their traversal. Applicants respectfully disagree that the polynucleotide sequences of the instant application would be considered of the complexity that merits restriction to a single sequence in contradiction to the expressed USPTO policy of examining ten sequences, as set forth in the Manual of Patent Examining Procedure. (*See* MPEP, 8th ed., August 2001, Section 803.04, page 800-10.) However, in order to facilitate prosecution Applicants have removed non-elected sequences from the claims.

III. The Rejection of Claim 1 under 35 U.S.C. § 101

Claims 1-2 were rejected under 35 U.S.C. § 101, because the claimed invention is allegedly not supported by either specific and/or substantial utility or a well-established utility. Office Action at page 2. Applicants respectfully traverse this rejection.

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including "isolation of polypeptides," use "as markers," and as "hybridization probes, primers, [and for] the isolation of full-length cDNAs or genes." Office Action at page 2. However, despite this admission and numerous uses cited throughout the specification, the examiner contends that none of these utilities constitutes a "substantial" or "specific" utility as defined in the Interim Guidelines.

Applicants respectfully disagree. The application of the Interim Guidelines ignores the presently disclosed utilities and contravenes well-established doctrines of utility developed in the courts. It is well-established law that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." *Raytheon Co. v. Roper Corp.,* 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983). As acknowledged by the Examiner, the specification describes multiple objectives and utilities that are met by the present invention. For example, the claimed nucleic acid molecules are useful in determining the presence of polymorphisms, isolating specific promoter sequences, and to obtain nucleic acid homologues, *etc.* (*see, e.g.,* specification, beginning at page 33, under heading "Uses of the Agents of the Invention").

Many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell, or organism. Significantly, the utility of a microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.,* the claimed nucleic acid molecules may be used to identify and characterize nucleic acid molecules within a sample, cell, or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed sequences possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner attempts to undermine the existing utilities by stating that they are "generally applicable to any nucleic acid," Office Action at page 2, and "generic in nature and applicable to a myriad of such compounds." *Id.* at page 3. In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renshaw PLC,* 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...").

Such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.,* hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty,* 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

Applicants note that the claimed nucleic acid molecules encompass many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequence and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid molecules exhibit the requisite utility under 35 U.S.C. § 101.

The Examiner states that the credibility of the presently asserted utilities has not been assessed. Office Action at page 3. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question operability – [she] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert,* 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 2107.01 ("Office personal are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). Here, the Examiner has not even attempted to meet this burden. Thus, the Examiner's admission that the credibility of the disclosed utilities is not challenged is tantamount to an admission that no proper rejection has been made.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging most of the presently asserted utilities. An invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the rejection under 35 U.S.C. § 101 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

IV. The Rejection of Claims 1-2 under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 1-2 were rejected under 35 U.S.C. § 112, first paragraph, as not being enabled by the specification, because the claimed invention allegedly lacks utility (*i.e.*, an invention with no utility cannot be enabled). Office Action at page 4. Applicants respectfully traverse this rejection, and note that this rejection has been overcome by the foregoing arguments regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph, is improper. Reconsideration and withdrawal are respectfully requested.

V. The Rejection of Claim 1-2 under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 1-2 were also rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking an adequate written description. Office Action at page 4. Applicants respectfully traverse this rejection.

The Examiner does not contest that Applicants have disclosed SEQ ID NO: 1 and, as such, have *per se* met the written description provision of 35 U.S.C. § 112, first paragraph with respect to this sequence. However, the Examiner contends that the specification "provides insufficient written description to support the genus encompassed by the claim." Office Action at page 4. According to the Examiner, claims 1-2 lack sufficient written description because "[w]ith the exception of SEQ ID NO: 1 the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides". *Id.* at page 5. Such an assertion is unfounded.

As the Examiner notes, the purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this

purpose, Applicants need not "describe," in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989).

A related, and equally well-established principle of patent law is that claims "may be broader that the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-Mar-Co.*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Thus, in order for Applicants to describe the molecules encompassed by the claims, it is not required that each and every aspect of those nucleic acid molecules be disclosed. *In re Alton,* 76 F.3d 1168, 1175 (Fed. Cir. 1996) (adequate written description is provided if a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing even if every nuance of the claims is not explicitly described in the specification).

Furthermore, an adequate written description of a genus of nucleic acids, such as recited in claims 1 and 2, may be achieved by either "a recitation of a representative number of [nucleic acid molecules], defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus." *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569 (Fed. Cir. 1997). The feature relied upon to describe the claimed genus must be capable of distinguishing members of the claimed genus from non-members. *Id.*

The Examiner contends that "[w]ith the exception of SEQ ID NO: 1 the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides". Office Action at page 5. According to the Examiner's argument, proper written description support for a claim directed to a nucleic acid sequence requires nothing less than the actual disclosure of every sequence encompassed by that claim. Applicants respectfully disagree. The present claims define, with a high degree of specificity, chemical properties commonly possessed by members of the genus that

distinguishes them from others. In particular, Applicants have provided a detailed chemical structure, *i.e.*, the nucleic acid sequence of SEQ ID NO: 1. Moreover, nucleic acid molecules falling within the scope of the present claims are readily identifiable – they comprise a nucleic acid molecule having a nucleic acid sequence of SEQ ID NO: 1. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the present specification. Accordingly, there is no deficiency in the written description support for claims 1 and 2.

On the basis of the foregoing, it is clear that claims 1 and 2 satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. Thus, reconsideration and withdrawal of this rejection is respectfully requested.

VII. The Rejection of Claims 1-2 under 35 U.S.C. § 112, Second Paragraph

Claims 1 and 2 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Office Action at page 6. According to the Examiner, claims 1-2 are indefinite because they fail to point out "what is included or excluded by the claim language 'substantially.' " *Id.* Applicants respectfully disagree.

Applicants respectfully point out that the use of a relative term does not make a claim *per se* indefinite. The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. *Seattle Box Co. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 826, 221 U.S.P.Q. 568, 574 (Fed. Cir. 1984); MPEP § 2173.05(b). In addition, use of the modifier "substantial" does not render a claim limitation indefinite provided that the specification contains guidelines sufficient to teach one of ordinary skill in the art what was meant by the limitation. *See, e.g., In re Mattison,* 509 F.2d 563, 565, 184 U.S.P.Q. 484, 486 (C.C.P.A. 1975); *Andrew Corp. v. Gabriel Electronics,* 847 F.2d 819, 822, 6 U.S.P.Q.2d 2010, 2013, (Fed. Cir. 1988); MPEP § 2173.05(b).

In the present application disclosure, the phrase "substantially purified" is defined in the specification as follows:

> The term "substantially purified," as used herein, refers to a molecule separated from substantially all other molecules normally associated with it in its native state. More preferably a substantially purified molecule is the predominant species present in a preparation. A substantially purified molecule may be greater than 60% free, preferably, 75% free, more preferably 90% free, and most preferably 95% free from other molecules (exclusive of solvent) present in the natural mixture. The term "substantially purified" is not intended to encompass molecules present in the native state.

Specification at page 16, line 22 through page 17, line 4. Applicants respectfully assert that, consistent with the requirement of MPEP § 2173.05(b), the specification contains guidelines sufficient to teach the meaning of "substantially purified" to one of ordinary skill in the art. Specifically, this definition is sufficient to convey to a person of ordinary skill in the art the meaning of this phrase because these guidelines include multiple verbal descriptions (for example, "separated from substantially all other molecules normally associated with it in its native state," and "the predominant species present in a population"), numerical ranges of purity, as well as an explicit disclaimer of a definition encompassing molecules present in their native state.

For the foregoing reasons, Applicants respectfully assert that the specification contains guidelines sufficient to teach the meaning of the claim language "substantially" to one of ordinary skill in the art, and thus, the rejection of claim 1 and 2 under 35 U.S.C. § 112, second paragraph, is improper. Reconsideration and withdrawal of this rejection is respectfully requested.

Conclusion

In view of the above, the presently pending claims are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass the application to issue. The Examiner is encouraged to contact the undersigned at (202) 942-5000 with respect to any unresolved issues remaining in this application.

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicants do not believe that any fees are due at this time. However, if any fees under 37 C.F.R. §§ 1.16 or 1.17 are required in the present application, then the Commissioner is hereby authorized to charge such fees to Deposit Account No. 50-2387, referencing docket number 16517.251.

Respectfully submitted,

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